Ref. 6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

OCT 21 1996

Mr. Ted Jacoby, Jr.
T.C. Jacoby & Company, Inc.
3701 South Lindbergh Boulevard
St. Louis, Missouri 63127

Dear Mr. Jacoby:

This letter is in response to your correspondence, dated May 1, 1996, to Ms. Elizabeth J. Campbell, Director, Division of Programs and Enforcement Policy, Office of Food Labeling, and your subsequent meeting on August 27, 1996, to discuss the following issues: (1) the labeling of the dairy derived product which results when milk is subjected to processing in an ultrafiltration system and (2) the labeling of cheese that is made from an ultrafiltered milk product.

You refer to the ultrafiltered milk product that results from subjecting milk to processing in an ultrafiltration system and that is subsequently used for processing into cheese as the "retentate." Because some lactose, water, minerals, and water-soluble vitamins are removed from the milk by processing the milk in an ultrafiltration system, this retentate contains higher concentrations of protein, fat, and lactose and lower concentrations of minerals and water-soluble vitamins than milk. You state that the firm Bongards Creamery, Bongards, Minnesota, wishes to use this retentate in the manufacture of Cheddar cheese. You further indicated that retentate is produced solely in-house by other companies as a step in the manufacture of various cheeses.

We recognize that cheesemaking technology has changed tremendously in the last 30 years. Cheddar cheese is one of the standardized cheeses for which "alternate make procedures" have been provided under 21 CFR 133.113(a)(1). Under alternate make procedures, Cheddar cheese may be prepared by any procedure which produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional cheese making process (i.e., the procedures set forth in the standard under 21 CFR 133.113(a)(3)).

From the information that you provided us, it is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing

in an ultrafiltration system is nutritionally equivalent to and is physically and chemically identical to the Cheddar cheese prepared by the procedures set forth in the standard under 21 CFR 133.113(a)(3). Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese by Bongards Creamery on the limited basis described in your May 1, 1996, correspondence. However, if it is found that the resultant cheese differs from that produced traditionally, use of the retentate in the cheese would necessitate a petition to amend the definition and standard of identity for the cheese.

Additionally, we are of the opinion at this time that the retentate that results when milk is subjected to processing in an ultrafiltration system may be declared as "milk" in the ingredient statement on the label of the Cheddar cheese produced at Bongards Creamery, provided that the Cheddar cheese manufactured from this retentate is at least nutritionally equivalent to and has the same physical and chemical properties, as the cheese prepared by the procedures specifically set forth in the applicable standard. However, we do not consider the term "milk" unqualified to be an appropriate ingredient declaration for the retentate produced by an ultrafiltration system, when it is used in food products, other than the standardized cheeses such as Cheddar cheese for which alternative make procedures have been specifically provided in the regulations.

Further, while in interstate commerce, the retentate is subject to the applicable requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act and the regulations promulgated under the authority of the Act, and in addition, it must comply with applicable requirements of the Grade "A" Pasteurized Milk Ordinance (PMO) (1995 Revision). We remind you that Section 4 of the PMO requires that each shipment of the retentate be accompanied by a shipping statement that contains the name of the product, in compliance with the applicable requirements of the FD&C Act and regulations promulgated under the authority of the Act. As you are aware, the retentate does not meet the requirements of the definition and standard of identity for milk in 21 CFR 131.110; therefore, the retentate may not be labeled with the term "milk" unqualified. While we would not object to use of the term "milk" as a part of the name given to the retentate, the retentate needs to be labeled with an appropriately descriptive name that accurately reflects its true identity and is not false or misleading. We caution you that this name must clearly distinguish the retentate from the standardized food milk in terms of all salient characteristics (nutritional value, chemical composition, etc.), and the retentate must be labeled so that the

purchaser can readily determine how the retentate differs from milk.

We hope that this information is helpful.

Sincerely yours,

Margaret E. Cole

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